**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| **IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION** | **MDL No. 2875** |
| **THIS DOCUMENT RELATES TO ALL CASES** | **HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)(KMW)** |

# PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' *DAUBERT* MOTION TO EXCLUDE TESTIMONY OF LAUREN J. STIROH, PH.D.

MEYER WILSON, CO., LPA
900 Camp Street
Suite 337
New Orleans, LA 70130

On the Brief:
Layne C. Hilton

## I. INTRODUCTION

Dr. Stiroh proffers two overarching opinions, only one of which is the subject of this *Daubert* motion. The first is that VCDs had greater-than-zero economic value because they purportedly delivered at least some therapeutic value. This Court allowed that opinion at class certification, and Plaintiffs do not challenge it here.

Dr. Stiroh's second overarching opinion is the one now before the Court. The flawed syllogism for Dr. Stiroh's second opinion is as follows: (i) assume VCDs were off the market sooner; (ii) in that but-for world, Plaintiffs would have purchased alternative products; (iii) therefore, Plaintiffs' damages for actually purchasing VCDs should be reduced (or entirely extinguished) by how much those alternative products would have cost TPPs. This opinion is utterly unreliable, unhelpful, and not based on sufficient facts or data. It should be excluded under *Daubert* (and under Fed. R. Evid. 401, 403) for at least two principal reasons.

***First***, Dr. Stiroh does not apply the correct measure of damages. As Defendants themselves have repeatedly argued as recently as a few weeks ago, the measure of damages, under either the benefit-of-the-bargain or out-of-pocket approach, is "the difference between the price paid and the actual value received." *See* D.E. 2261 at 35-36. That is, the appropriate, and indeed only, measure of damages here quite simply is: how much were the contaminated VCDs really worth? That humble question solely focuses on the value of the VCDs themselves. The cost

of "alternative products" has no place whatsoever in the analysis. For this reason alone, Dr. Stiroh's opinion about the cost of "alternative products" in a but-for world is totally irrelevant, unhelpful, and unreliably applied to the facts of this case.

***Second***, neither Dr. Stiroh nor Defendants have adduced any admissible evidence in the record of the "market factors" they claim a jury should consider, such as: the existence of alternative hypertension drugs interchangeable with the at-issue VCDs, the existence of nitrosamine-free valsartan products on the market, the costs associated with these products, and if purchased, what price the TPP class would have paid for these products. Dr. Stiroh simply declares that some unspecified class members, at some indeterminate time period, would have paid unquantified amounts, for some other unnamed alternative products. Dr. Stiroh's conjecture and speculation, devoid of any methodology and outside the scope of proper rebuttal, must be excluded.

## II. ARGUMENT

### A. Dr. Stiroh's Opinions about the "But-For" World Are Irrelevant to the Parties' View on the Proper Measure of Damage

As noted *supra*, Defendants concede that the applicable measure of damages in this case focuses solely on the value of the VCDs purchased by class members. For instance, at summary judgment, Defendants said the benefit-of-the-bargain approach measures "the difference between the price paid and the value of the property had the representation been true." D.E. 2261 at 35 (quotations omitted).

Defendants defined the out-of-pocket approach identically: "out-of-pocket damages represent the difference between the price paid and the actual value received." *Id.* at 36 (quotations omitted). Thus, according to Defendants, what should be measured under either approach is how much class members paid for VCDs against how much those VCDs were really worth (for example, zero, as Plaintiffs' expert Dr. Conti opines). This is what the jury will be deciding in a few weeks.

Because the parties generally agree on what the proper focus is for measuring damages, Dr. Stiroh's speculative opinions about how much "alternative medications" might have cost in a "but-for" world is entirely irrelevant, unhelpful, and unreliable. Dr. Stiroh's failure to connect her "alternative medications" opinion with the actual facts and theories in this case render it inadmissible, *see, e.g.*, *Comcast Corp. v. Behrend*, 569 U.S. 27 (2013), not to mention contrary to law. *See, e.g.*, *Sprint Commc'ns Co. L.P. v. Cox Commc'ns Inc.*, 302 F. Supp. 3d 597, 619 (D. Del. 2017) (opinion "contrary the law … [is] unhelpful and likely to confuse a jury") (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)).

**B. Dr. Stiroh's Opinions Are Not Proper Rebuttal Testimony**

Furthermore, Dr. Stiroh's opinions regarding the "but-for" world are not even truly within the scope of a proper rebuttal report. Dr. Conti's opinions did not include, in any way at all, a recitation or discussion about the economic treatment of the TPPs had the VCDs not been sold on the market – she simply set about to

ascertain the economic value of those VCDs, manufactured in the manner they were manufactured, with NDMA. Incidentally, this is the same approach this Court has noted multiple times throughout this litigation.

Dr. Stiroh's other primary opinion not the subject of this *Daubert* motion—*viz.*, that the VCDs had some non-zero economic value because they purportedly delivered some therapeutic value—at least falls within a proper rebuttal of Dr. Conti's opinions. *See, e.g.*, *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, 2023 U.S. Dist. LEXIS 21112, at *260 (D.N.J. Feb. 8, 2023) (this Court, noting at class certification, that "Dr. Stiroh disagrees with Dr. Conti's determination that the sold VCDs were worthless and had zero value at the time of sale. This is so because the VCDs continued to be sold/consumed for a period of time after the recall, thereby demonstrating their therapeutic effectiveness.").

But Dr. Stiroh's second overarching opinion, which is a freewheeling dive into unspecified "market factors" that might have played out in a "but-for" world in which VCDs were not sold and class members would have bought alternative products instead, has nothing to do with the value of the at-issue VCDs. Purported "market factors" are outside the scope of Dr. Conti's report (which set forth to calculate the value of the at-issue VCDs). This is not an antitrust pay-for-delay case, where damages might be measured as the difference in value between two products (such as a branded drug and a generic drug). Nor is this a "lost services" case, in

which damages might be measured by the cost for comparable services, evidence of which might include how much alternative services cost. The one and only issue, agreed on by all parties and this Court, is how much were VCDs purchased for in the real world *actually* worth. And what VCDs were actually worth is a fact question focused on the VCDs themselves and only themselves, not as compared to some other product.

Rather than "rebuttal testimony," Dr. Stiroh is trying to present a new, affirmative theory—and one which inaptly tries to fit a round-peg into a square hole by grafting helter-skelter antitrust-case market analysis concepts into this completely different case. Consequently, in offering this affirmative testimony, Dr. Stiroh was required to undertake the modeling to *reliably* assess the but-for world. But she never did that. She does not identify or apply any methodology (let alone a reliable one) to sufficient underlying facts and (data about her vaguely-referenced "market factors" and "alternative products." Her failure to do so renders her affirmative new opinions chiefly unreliable under *Daubert.*[1]

[1] Moreover, allowing expert testimony on irrelevant "market factors" and "alternative products" will mislead and confuse the jury, and unduly delay trial by spiraling into a sideshow about how much alternative products costed, when, and which class members might have purchased in a but-for world devoid of VCDs. Dr. Stiroh's infirm theory not only runs contrary to law, but to common sense as well. Take *any* case involving a claim for damages for a product that did not work as promised. A defendant is not entitled to an 'offset' of the plaintiff's damages on the notion that the plaintiff has zero damages because they would have just bought a different product that did work. Unsurprisingly, neither Dr. Stiroh nor Defendants

### C. Rebuttal Testimony Cannot Rest on Purely Hypothetical Facts Outside of the Record

Even if, *arguendo*, the Court finds Dr. Stiroh's unreliable and entirely irrelevant testimony within the scope of a rebuttal report, the testimony must still be excluded for failing to rely on the actual factual record.[2] When proffering a rebuttal, experts are not permitted to rely on incorrect factual assumptions or make the mere ipse dixit assertions like those made by Dr. Stiroh. *See APEX Fin. Options, LLC v. Gilbertson*, Civil Action No. 19-046-WCB-SRF, 2022 U.S. Dist. LEXIS 20696, at *13 (D. Del. Jan. 31, 2022) (excluding a Defendant's rebuttal expert report because it, among other things, contained no citations to "any document in the factual record"); *Elcock v. Kmart Corp.*, 233 F.3d 734, 755 (3d Cir. 2000) (excluding an expert's testimony unless the assumptions made by the expert were "accompanied by a sufficient factual foundation."). Because Dr. Stiroh's opinions regarding the cost of alternative medications for the economic modeling of her counterfactual "but-for" world are untethered from the factual record, they must be excluded.

---

cite a single case for this outlandish proposition, because such a proposition would render consumer litigation totally moot.

[2] It should be noted that almost five years ago in this litigation, the Plaintiffs sought discovery from Defendants regarding their manufacture and/or sale of other drugs (namely, uncontaminated valsartan products, and other hypertension medications, i.e., "alternative products," that might have had the same or similar manufacturing processes as the at-issue VCDs). Defendants vociferously fought the disclosure of this discovery, arguing that it was totally irrelevant to the case. The Court agreed with Defendants, and precluded discovery of these "other drugs." *See* D.E. 309. Defendants cannot have it both ways.

## III. CONCLUSION

For the foregoing reasons, the Court should exclude Dr. Stiroh's opinions on how a TPP would have acted in the "but-for" world and testimony regarding the TPPs purchase of "alternative products."

Dated: March 6, 2024

Respectfully,

By: */s/ Layne C. Hilton*
Layne C. Hilton
MEYER WILSON. CO., LPA
900 Camp Street, Suite 337
New Orleans, LA 70130
614-255-2697
lhilton@meyerwilson.com

*On Behalf of MDL PEC and TPP Trial Plaintiffs*

## CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of March, 2024, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system.

*/s/ Layne C. Hilton*
Layne C. Hilton